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Dated 18 April 2007

20 FEB 2003

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P01/7700 0.00-0303870.0

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0303870.0

20 FEB 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

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Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

06188221004

4. Title of invention

PRE-METERED DOSE MAGAZINE FOR BREATH-ACTUATED DRY POWDER INHALER

5. Name of your agent (if you have one)

MARTIN A. HAY

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Patents ADP number (if you know it) 07710858001

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6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and (if you know it) the or each application number

Country

Priority application number  
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Date of filing  
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing  
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I/We request the grant of a patent on the basis of this application

Signature

Date:

19<sup>th</sup> February 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

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**PRE-METERED DOSE MAGAZINE  
FOR BREATH-ACTUATED DRY POWDER INHALER**

Inventors:  
(Attorney Docket: NHC0071)

**Cross-Reference to Related Applications**

[0001] The present application is related to co-pending U.S. patent application serial number 09/888,277, filed on June 23, 2001, which claims priority to provisional U.S. patent application serial no. 60/213,669, filed June 23, 2000 (entitled "Pre-Metered Dose Magazine for Breath-Actuated Dry Powder Inhaler"), and provisional U.S. patent application serial no. 60/213,382, filed June 23, 2000 (entitled "De-Agglomerator for Breath-Actuated Dry Powder Inhaler"). Each of these applications is assigned to the assignee of the present invention and incorporated herein by reference.

**Field of the Invention**

[0002] The invention relates to a breath-actuated dry powder inhaler for administering dry powder medicament to a patient. More particularly, the present invention relates to a magazine having a plurality of individually separated, pre-metered doses for a breath-actuated dry powder inhaler and a method for providing pre-metered doses of dry powder medicament for inhalation by a patient.

**Background of the Invention**

[0003] Metered dose medicament inhalers are well known for dispensing medicament to the lungs of a patient. In most cases, the inhalers include a reservoir containing dry powder medicament in bulk form, and means for metering the medicament from the reservoir in discrete amounts for inhalation by a patient.

[0004] For example, U.S. Patent No. 5,503,144, which is assigned to the assignee of the present invention and incorporated herein by reference, shows a breath-actuated dry-powder inhaler having a medicament reservoir. The reservoir contains dry powder medicament in bulk form, and the inhaler includes a metering chamber for removal of the powdered medicament from the reservoir in discrete amounts. The inhaler also includes an air inlet for entraining the removed powdered medicament through a mouthpiece upon patient inhalation.

[0005] While the reservoir and metering chamber of the inhaler shown by U.S. Patent No. 5,503,144 properly function to dispense discrete amounts of powdered medicament to a patient, there is desired an inhaler having pre-metered doses of powdered medicament. Providing the powdered medicament in pre-metered doses will further ensure that the medicament is consistently dispensed to a patient in precise doses.

[0006] In particular, a device and method are desired for providing individually sealed, pre-metered doses of dry powder medicament for inhalation by a patient through a dry powder inhaler and, in particular, a breath-actuated, dry powder inhaler.

[0007] An improved breath-actuated, dry powder inhaler, which substantially de-agglomerates and micronizes pre-metered doses of medicament is also desired to ensure that particles of the medicament are small enough for adequate penetration of the medicament into a bronchial region of a patient's lungs during inhalation.

### Summary of the Invention

[0008] The present invention provides a pre-metered dose assembly for consistently supplying precise doses of medicament to a breath-actuated dry powder inhaler. The assembly includes a cap defining a dry powder delivery passageway for providing air to a dry powder supply port of a swirl chamber of a breath-actuated dry powder inhaler, and a magazine including a plurality of reservoirs for holding pre-metered doses of dry powder. One of the magazine and the cap is movable with respect to the other of the magazine and the cap for sequentially positioning the reservoirs within the delivery passageway of the cap. A breath-induced low pressure at an outlet port of the swirl chamber of the inhaler causes an air flow through the dry powder delivery passageway of the assembly and into the dry powder supply port of the swirl chamber. The air flow entrains dry powder from the reservoir positioned in the passageway for inhalation by a patient using the inhaler.

[0009] The present invention also provides a breath-actuated dry powder inhaler including the pre-metered dose assembly in combination with a de-agglomerator for breaking up aggregates and micronizing particles of dry powder prior to inhalation of the powder by a patient. The de-agglomerator includes an inner wall defining a swirl chamber extending along an axis from a first end to a second end, a dry powder supply port, one or more primary air flow inlet ports, and an outlet port. The supply port is at the first end of the swirl chamber for providing fluid communication

between the dry powder delivery passageway of the pre-metered dose assembly and the first end of the swirl chamber. The primary air flow inlet ports are in the inner wall of the swirl chamber adjacent to or near the first end of the swirl chamber and provide fluid communication between a region exterior to the de-agglomerator and the swirl chamber. The outlet port provides fluid communication between the second end of the swirl chamber and a region exterior to the de-agglomerator.

**[0010]** A breath-induced low pressure at the outlet port of the de-agglomerator causes air flows into the swirl chamber through the dry powder supply port and the inlet port. The air flows collide with each other and with the wall of the swirl chamber prior to exiting through the outlet port, such that any powder entrained in the air flows is broken down and micronized. The de-agglomerator further includes vanes at the first end of the swirl chamber for creating additional collisions and impacts of entrained powder.

**[0011]** Further features and advantages of the presently disclosed pre-metered dose magazine and method for providing pre-metered doses will become more readily apparent to those having ordinary skill in the art to which the present invention relates from the following detailed description and attached drawings.

### Brief Description of the Drawings

[0012] So that those having ordinary skill in the art will more readily understand how to construct a pre-metered dose magazine and a breath-actuated, dry powder inhaler in accordance with the present invention, exemplary embodiments are described in detail below with reference to the drawing figures wherein:

[0013] FIG. 1 is a side and top isometric view of an exemplary embodiment of a breath-actuated, dry powder inhaler according to the present invention including a housing having a mouthpiece cover shown in a closed position;

[0014] FIG. 2 is a front and top isometric view of the inhaler of FIG. 1, with the mouthpiece cover shown in an opened position to expose a mouthpiece of the inhaler;

[0015] FIG. 3 is a bottom plan view of an upper portion of the housing of the inhaler of FIG. 1;

[0016] FIG. 4 is a top plan view of a lower portion of the housing of the inhaler of FIG. 1;

[0017] FIG. 5 is a top plan view of a dose magazine of the inhaler of FIG. 1;

[0018] FIG. 6 is a side elevation view of the dose magazine of the inhaler of FIG. 1;

[0019] FIG. 7 is a top plan view of a cup-like base of a de-agglomerator of the inhaler of FIG. 1;

[0020] FIG. 8 is a bottom isometric view of a top piece of the de-agglomerator of the inhaler of FIG. 1;

[0021] FIG. 9 is a side elevation view of the cup-like base of the de-agglomerator of the inhaler of FIG. 1;

[0022] FIG. 10 is a top plan view of the mouthpiece cover of the inhaler of FIG. 1, showing a magazine advancement rake pivotally extending from the cover;

[0023] FIG. 11 is a side elevation view of the mouthpiece cover and advancement rake of the inhaler of FIG. 1;

[0024] FIG. 12 is a top plan view of an exemplary embodiment of a dose magazine constructed in accordance with the present invention;

[0025] FIG. 13 is a sectional view of the dose magazine taken along line 13--13 of FIG. 12;

[0026] FIG. 14 is a top plan view of the dose magazine of FIG. 12, shown with an upper foil layer removed;

[0027] FIG. 15 is a top plan view of another exemplary embodiment of a dose magazine constructed in accordance with the present invention;

[0028] FIG. 16 is a sectional view of the dose magazine taken along line 16--16 of FIG. 15;

[0029] FIG. 17 is a top plan view of an additional exemplary embodiment of a dose magazine constructed in accordance with the present invention;

[0030] FIG. 18 is a sectional view of the dose magazine taken along line 18--18 of FIG. 17;

[0031] FIG. 19 is a top perspective view of a portion of a further exemplary embodiment of a dose magazine constructed in accordance with the present invention, and including a foil removal mechanism;

[0032] FIG. 20 is a top plan view of a further exemplary embodiment of a dose magazine constructed in accordance with the present invention;

[0033] FIG. 21 is a sectional view of the dose magazine taken along line 21--21 of FIG. 20, showing a deployable medicament piston of the dose magazine;

[0034] FIG. 22 is a sectional view of exemplary embodiments of a dose magazine, a medicament piston, and an actuator, which is shown deploying the piston, all constructed in accordance with the present invention;

[0035] FIG. 23 is a perspective view of the actuator of FIG. 22;

[0036] FIG. 24 is a side perspective view of additional exemplary embodiments of a dose magazine, a mouthpiece cover and an actuator, all constructed in accordance with the present



invention, and wherein the actuator is adapted to cause a medicament piston to be deployed from the magazine upon the mouthpiece cover being opened;

[0037] FIG. 25 is a front perspective view of the dose magazine, the mouthpiece cover and the actuator of FIG. 24;

[0038] FIG. 26 is a sectional view of a further exemplary embodiment of a dose magazine, a medicament piston, and an actuator shown deploying the piston, all constructed in accordance with the present invention;

[0039] FIGS. 27 through 30 are side views of various exemplary embodiments of medicament pistons constructed in accordance with the present invention;

[0040] FIG. 31 is a side elevation view of another exemplary embodiment of a medicament piston constructed in accordance with the present invention;

[0041] FIG. 32 is a top plan view of the medicament piston of FIG. 31;

[0042] FIG. 33 is a side elevation view of an additional exemplary embodiment of a medicament piston constructed in accordance with the present invention;

[0043] FIG. 34 is a top plan view of the medicament piston of FIG. 33;

[0044] FIG. 35 is a side elevation view of another exemplary embodiment of a medicament piston constructed in accordance with the present invention;

[0045] FIG. 36 is a top plan view of the medicament piston of FIG. 35;

[0046] FIG. 37 is a side elevation view of an additional exemplary embodiment of a medicament piston constructed in accordance with the present invention;

[0047] FIG. 38 is a top plan view of the medicament piston of FIG. 37;

[0048] FIG. 39 is a top perspective view of a further exemplary embodiment of a dose magazine constructed in accordance with the present invention;

[0049] FIG. 40 is a side elevation view of exemplary embodiments of a dose magazine, an actuator for causing deployment of a medicament piston from the magazine, and an adjustment

mechanism for adjusting the magnitude of deployment produced by the actuator, all constructed in accordance with the present invention;

[0050] FIG. 41 is a top plan view of a further exemplary embodiment of a dose magazine constructed in accordance with the present invention and including sets of deployable medicament pistons;

[0051] FIG. 42 is a side perspective view of a portion of the dose magazine of FIG. 41, wherein a set of the medicament pistons is shown deployed, or extended upwardly, from a top surface of the magazine;

[0052] FIG. 43 is a side elevation view of a portion of the dose magazine of FIG. 41, showing a set of actuators for causing deployment of a set of the medicament pistons from the magazine, and wherein the actuators can be manipulated as desired to cause one or more of the pistons to be deployed;

[0053] FIG. 44 is an end elevation view of a portion of the dose magazine of FIG. 41, showing the set of actuators, wherein two out of four of the actuators have been manipulated to cause deployment of pistons;

[0054] FIG. 45 is a top and side perspective view of a further exemplary embodiment of a dose magazine constructed in accordance with the present invention and including bores for receiving deployable medicament pistons, and wherein the bores extend radially with respect to an axis of the magazine;

[0055] FIG. 46 is a sectional view of one of the bores of the dose magazine of FIG. 45;

[0056] FIG. 47 is a top and side perspective view of another exemplary embodiment of a dose magazine constructed in accordance with the present invention and including bores for receiving deployable medicament pistons, wherein the bores extend radially and at an angle with respect to an axis of the magazine;

[0057] FIG. 48 is a sectional view of one of the bores of the dose magazine of FIG. 47;

[0058] FIG. 49 is a top plan view of an additional exemplary embodiment of a dose magazine constructed in accordance with the present invention and including bores for receiving deployable medicament pistons, wherein the bores extend tangentially with respect to the magazine;

[0059] FIG. 50 is a top and side perspective view of another exemplary embodiment of a dose magazine constructed in accordance with the present invention and including bores for receiving deployable medicament pistons, wherein the bores are positioned at an outer circumference of the magazine and extend axially with respect to an axis of the magazine;

[0060] FIG. 51 is a top plan view of a further exemplary embodiment of a rotatable dose magazine constructed in accordance with the present invention and including radially extending teeth for engaging a pawl, as shown, to prevent reverse rotation of the magazine and to provide an indication of the advancement of a final dose of the magazine;

[0061] FIGS. 52 and 53 are side elevation views of an exemplary embodiment of a pawl constructed in accordance with the present invention, for engaging a dose magazine;

[0062] FIG. 54 is a top plan view of another exemplary embodiment of a rotatable dose magazine constructed in accordance with the present invention and including radially extending medicament dose containers and a fixed blade for successively opening the dose containers upon rotation of the magazine;

[0063] FIG. 55 is a side elevation view of an exemplary embodiment of a straw constructed in accordance with the present invention and including medicament dose containers, and wherein an exemplary embodiment of a blade constructed in accordance with the present invention for successively opening the dose containers upon linear movement of the straw is shown;

[0064] FIG. 56 is a side elevation view of another exemplary embodiment of a straw constructed in accordance with the present invention and including medicament dose containers, and wherein parallel layers of the straw are peeled apart and wound to cause linear movement of the straw and successively open the dose containers;

[0065] FIG. 57 is a side elevation view of an exemplary embodiment of a medicament dose carrier constructed in accordance with the present invention and having doses of medicament

attached to a surface of the carrier, and wherein the carrier is shown being worked around a sharp corner to release doses of the medicament from the carrier as the carrier is bent around the corner;

[0066] FIG. 58 is a side elevation view of a further exemplary embodiment of a straw constructed in accordance with the present invention and including medicament dose containers, and wherein the straw is shown being worked around a sharp corner to successively open the dose containers as the containers are bent around the corner; and

[0067] FIGS. 59 and 60 are sectional views of portions of a filling nozzle and a dry powder medicament dose magazine illustrating exemplary embodiments of a method for filling reservoirs of the magazine with medicament carried out in accordance with the present invention.

#### **Detailed Description of Exemplary Embodiments**

[0068] FIGS. 1 and 2 show an exemplary embodiment of a dry powder inhaler 10 constructed in accordance with the present invention. The dry powder inhaler 10 includes a pre-metered dose magazine 12 (not viewable in FIGS. 1 and 2 but shown in FIGS. 5 and 6) that consistently furnishes precise doses of dry powder, e.g., a dry powder medicament or medicament composition, for inhalation by a patient using the dry powder inhaler 10.

[0069] During use, the patient opens a mouthpiece cover 14 of the inhaler 10, inhales, then closes the cover. The mouthpiece cover 14 is also shown in FIGS. 10 and 11. The action of opening the cover 14 advances the pre-metered dose magazine 12, shown in FIGS. 5 and 6, presenting a dose for inhalation. If the cover 14 is closed without taking the dose, that dose is contained within the inhaler 10, and is not presented again for inhalation. Thus, there is no possibility for unintentional double dosing. Partial opening of the cover 14 will allow the user to see an indication of the number of doses remaining without advancing the magazine. Due to the individually sealed doses within the inhaler 10, a level of moisture protection is present with this inhaler.

[0070] As shown in FIGS. 1 and 2, the inhaler 10 includes a housing 18 having an upper portion 20 mated to a lower portion 22. FIG. 3 is a bottom plan view of the upper portion 20 of the housing 18, and FIG. 4 is a top plan view of the lower portion 22 of the housing. FIG. 5 and 6 show the dose magazine 12 of the inhaler 10 of FIGS. 1 and 2, and FIGS. 7 and 9 show a cup-like base 24 of a de-agglomerator of the inhaler 10 of FIGS. 1 and 2 and FIG. 8 shows a top piece 26 of the de-agglomerator. The cup-like base 24 is received in the lower portion 22 of the housing 18 and the

dose magazine 12 is received for rotation over the top piece 26 of the de- agglomerator and guided by the upper portion 20 of the housing 18.

[0071] During operation, the magazine 12 is movable with respect to the upper portion 20 of the housing 18 for sequentially positioning reservoirs 30 of the magazine 12 within a delivery passageway 32 of the upper portion. Then, a breath-induced low pressure at an outlet port 34 (shown in FIGS. 7 and 9) of the de-agglomerator causes an air flow, through the dry powder delivery passageway 32 into a dry powder supply port 36 (shown in FIG. 8) of the de-agglomerator. As shown best in FIG. 3, the passageway 32 of the upper portion 20 includes a venturi (or venturi-type restriction) that causes the velocity of the breath-induced air flow to increase. The air pressure in the venturi decreases as a result of the increased velocity, and the drop in pressure causes the pre-metered dose of dry powder to be dragged from the reservoir 30 aligned with the passageway 32, and entrained into the air flow traveling to the de-agglomerator.

[0072] Preferably, the magazine 12 is movable with respect to the upper portion 20 of the housing for sequentially positioning the dry powder reservoirs 30 of the magazine within the delivery passageway 32 of the upper portion. However, it should be understood that the magazine 12 could be made stationary, and the upper portion 20 made moveable with respect to the magazine for sequentially positioning the passageway over the reservoirs.

[0073] The magazine 12 is provided with an annular shape such that rotation of the annular magazine sequentially positions the plurality of the dry powder reservoirs 30 within the delivery passageway 32 of the upper portion 20 of the housing 18. The annular magazine 12 includes teeth 40 extending radially outwardly that are engaged by a pivotal rake 42 of the mouthpiece cover 14 for advancing the magazine 12 upon the cover 14 being opened. FIGS. 10 and 11 show the magazine advancement rake 42 pivotally extending from the cover 14. The engagement rake 42 engages the teeth 40 of the magazine 12 to rotate and advance the magazine 12 upon the mouthpiece cover 14 being opened.

[0074] The dry powder reservoirs 30 are provided in the top surface of the magazine 12 and are uniformly sized and spaced with respect to one another. The magazine 12 preferably includes a seal over the top surface for sealing the doses of dry powder in the reservoirs 30 of the magazine in a moisture resistant and airtight manner prior to the reservoirs being positioned within the delivery passageway 32 of the upper portion 20. The seal can comprise, for example, a metal foil secured to

the annular top surface of the magazine 12 with adhesive and covering the dry powder in the reservoirs 30 in a moisture resistant and airtight manner. The upper portion 20 of the housing 18 can include means for piercing the foil above each of the reservoirs 30 prior to the reservoirs being positioned within the delivery passageway 32 of the upper portion. The means for piercing can comprise, for example, a blade extending downward from the upper portion 20 of the housing 18 in front of the venturi of the delivery passageway 32.

[0075] It is intended that a manufacturer will fill the reservoirs 30 of the magazine 12 with properly metered individual doses of dry powder medicament, or medicament composition including medicament and a suitable particulate carrier such as lactose. The filled reservoirs 30 are then sealed in a moisture resistant and airtight manner, with the foil for example, and the magazine 12 and the upper portion 20 of the housing 18 are provided assembled as part of the inhaler 10. The inhaler 10 and the magazine 12 may be disposable. Alternatively, the dose magazine 12 may be removably insertable into a non-disposable inhaler 10 so that an empty magazine can be replaced by a full magazine.

[0076] Preferably, the magazine 12 is movable with respect to the upper portion 20 of the housing 18 through a plurality of discrete increments, wherein at each increment one of the plurality of the dry powder reservoirs 30 of the magazine is positioned within the delivery passageway 32 of the upper portion. In addition, the magazine 12 is preferably movable in a single direction only with respect to the housing 18, so that a user can access the reservoirs 30 in sequence, without being able to access one of the reservoirs 30 more than once. Furthermore, movement between the magazine 12 and the upper portion 20 of the housing is preferably prevented after all the dry powder reservoirs 30 of the magazine have been positioned in the delivery passageway 32 of the upper portion, to provide an indication to a patient that all of the doses of the magazine have been used. For example, the magazine 12 is provided with a radially inwardly extending catch 44, as shown in FIG. 5, that prevents further rotation of the magazine upon all of the reservoirs 30 passing through the delivery passageway 32 of the housing 18.

[0077] The inhaler 10 can also include an indicator for indicating the number of dry powder reservoirs 30 containing dry powder, i.e., the number of pre-metered doses remaining in the magazine 12. The indicator can comprise, for example, sequential printed numbers corresponding to the reservoirs 30 of the magazine 12 provided on the outer surface of the magazine, so that the

number of reservoirs that have passed through the delivery passageway 32 of the upper portion 20 of the housing 18 can be determined by partly opening the cover 14 (without causing the magazine to advance) and viewing the numbers on the magazine. Although not shown, the inhaler can also be provided with a lock for locking the mouthpiece cover 14 in an opened or a closed position upon the advancement of a final medicament reservoir of the magazine.

[0078] As its name implies, the de-agglomerator breaks down agglomerates of dry powder before inhalation of the dry powder by a patient. The de-agglomerator includes two diametrically opposed inlet ports 46, that extend in a direction substantially tangential to the circular cross-section of the swirl chamber formed within the de-agglomerator. As a result, air flows entering the chamber through the inlet ports 46, are at least initially directed transverse with respect to the chamber and collide with the air flow entering through the supply port to create a combined turbulence air flow.

[0079] The de-agglomerator includes vanes 48 at the first end of the swirl chamber 52. The vanes 48 are sized such that at least a portion of the combined air flows collide with oblique surfaces of the vanes. The geometry of the swirl chamber 52 causes the combined air flows and the entrained dry powder to follow a turbulent spiral path, or vortex, through the chamber. Thus, particles and any agglomerates of the dry powder constantly impact against the wall of the swirl chamber and collide with each other, resulting in a mutual grinding or shattering action between the particles and agglomerates. In addition, particles and agglomerates deflected off the oblique surfaces of the vanes 48 cause further impacts and collisions. The constant impacts and collisions cause any agglomerates of dry powder to break into additional particles, and cause the particles to be substantially micronized.

[0080] Upon exiting the swirl chamber 52, the direction of the combined air flow and the entrained dry powder is again changed through the outlet port 34, which extends through the mouthpiece 16 of the housing 18. The combined air flow and the entrained dry powder retain a swirl component of the flow, such that the air flow and the entrained dry powder spirally swirls through the outlet port 34. Since the micronized powder and any remaining agglomerates maintain the swirl imparted from swirl chamber, the swirling flow causes additional impacts in the outlet port 34 so as to result in further breaking up of any remaining agglomerates prior to being inhaled by a patient. The de-agglomerator, therefore, ensures that particles of the dry powder are small enough for adequate penetration of the powder into a bronchial region of a patient's lungs during inhalation.

[0081] The de-agglomerator is assembled from two pieces: the cup-like base 24 shown in FIGS. 7 and 9, and the top piece 26 shown in FIG. 8, which are connected together to form the swirl chamber 52 within the de-agglomerator. The cup-like base 24 is secured in the lower portion 22 of the housing 18 and defines the outlet port 34 and the inlet ports 46. The top piece 26 forms the vanes 48 and defines the supply port 36.

[0082] The top piece 26 also includes an upwardly extending cylindrical guide 50, and a chimney (not viewable) extending upwardly from the supply port 36 within the guide, as shown best in FIG. 8. The inner circumference of the annular magazine 12 is received coaxially on the guide 50, such that the magazine can be rotated about the guide. A hood of the upper portion 20 of the housing 18 is received over the chimney of the supply port 36 to connect the delivery passageway 32 of the upper portion 30 with the supply port 36 of the de-agglomerator.

[0083] The de-agglomerator, the magazine and the housing are preferably manufactured from a plastic such as polypropylene, acetal or moulded polystyrene, but may be manufactured from metal or another suitable material.

[0084] FIGS. 12 through 14 show an exemplary embodiment of a dose magazine 60 constructed in accordance with the present invention. The dose magazine 60 can be used for example with the inhaler of FIGS. 1 through 11. As shown in FIG. 14, the dose magazine 60 includes medicament reservoirs in the form of axial bores 62 for receiving medicament. As shown in FIGS. 12 and 13, the dose magazine 60 also includes a lower layer 64 of moisture resistant, air-tight material covering a lower surface of the magazine and an upper layer 66 of moisture resistant, air-tight material covering an upper surface of the magazine and enclosing medicament in the bores 62 of the magazine in a dry, air-tight manner. As shown best in FIG. 13, the upper layer 66 of moisture resistant, air-tight material can be provided with domes 68 over the medicament bores 62 so that a blade 70 can be positioned to successively cut open the domes 68 and release the medicament upon rotation of the magazine 60.

[0085] The moisture resistant, air-tight material can comprise, for example, metal foil secured to the magazine with adhesive. In addition, the foil layers may include selective adhesive, e.g., no adhesive positioned in contact with the medicament, in order to maintain dose uniformity. The moisture resistant, air-tight material can also comprise, for example, a laminate of metal foil secured a layer of plastic, which in turn is secured to the magazine with adhesive.



[0086] FIGS. 15 and 16 show another exemplary embodiment of a dose magazine 80 constructed in accordance with the present invention. As shown, the magazine 80 includes medicament reservoirs 82 and each medicament reservoir includes a lining 84 of moisture resistant, air-tight material, such as a metal insert or foil.

[0087] FIGS. 17 and 18 show an additional exemplary embodiment of a dose magazine 90 constructed in accordance with the present invention. As shown, the magazine 90 includes medicament reservoirs 92 formed in a trough 94 of a first material, such as plastic, which is formed in a trough 96 of moisture resistant, air-tight material, such as a metal. The metal trough 96 can be pre-formed via stamping or metal injection molding. The metal trough 96 can also be formed from a metal foil.

[0088] FIG. 19 shows a further exemplary embodiment of a dose magazine 100 constructed in accordance with the present invention, and including a foil removal mechanism 102. The foil removal mechanism comprises a rotatable winding wheel 102 which peels an upper layer 104 of moisture resistant, air-tight material, such as metal foil, from an upper surface of the magazine 100 as the magazine is rotated. As the foil 104 is peeled from the magazine 100, medicament reservoirs 106 are uncovered to allow inhalation of the medicament therein. The foil removal mechanism 102 can also be adapted and used to index the magazine 100.

[0089] FIGS. 20 and 21 show a further exemplary embodiment of a dose magazine 110 constructed in accordance with the present invention. The dose magazine 110 includes axial bores 112 containing deployable medicament pistons 114 sealed between layers 116, 118 of moisture resistant, air-tight material, such as metal foil. The pistons 114 each have at least one compartment 120 holding at least one dose of powder medicament, which are presented for inhalation upon the pistons 114 being pushed upwardly through the upper layer 116 of foil.

[0090] FIG. 22 shows exemplary embodiments of a dose magazine 130, a medicament piston 132, and an actuator 134, which is shown deploying the piston, all constructed in accordance with the present invention. FIG. 23 is a perspective view of the actuator 134 of FIG. 22. As the magazine 130 is linearly moved over the actuator 134, the actuator 134 successively pushes the pistons 132 upwardly through the upper layer 116 of foil to expose a compartment 136 containing a dose of medicament for inhalation.

[0091] FIGS. 24 and 25 show additional exemplary embodiments of a dose magazine 140, a mouthpiece cover 142 and an actuator 144, all constructed in accordance with the present invention, and wherein the actuator 144 is adapted to cause a medicament piston 146 to be deployed from the magazine 140 upon the mouthpiece cover 142 being opened.

[0092] FIG. 26 shows a further exemplary embodiment of a dose magazine 150, a medicament piston 152, and an actuator 154 shown deploying the piston, all constructed in accordance with the present invention. The medicament piston 152 includes multiple, vertically arranged shoulders 156a, 156b, 156c for holding dry powder medicament. By varying the amount that the piston 152 is extended through the upper layer 116 of foil, the amount of medicament for inhalation can be varied. For example, the piston 152 can be extended through the foil 116 so that only one 156a out of the three of the shoulders 156a, 156b, 156c of the piston extends above the foil so that a minimum dose is exposed for inhalation. Alternatively, the piston 152 can be extended through the foil 116 so that all of the shoulders 156a, 156b, 156c of the piston extend above the foil so that a maximum dose is exposed for inhalation.

[0093] FIGS. 27 through 30 show various exemplary embodiments of medicament pistons 160, 162, 164, 166 constructed in accordance with the present invention. The piston 160 of FIG. 27 includes vertically arranged shoulders 168a, 168b, 168c for supporting dry powder medicament, and the shoulders 168a, 168b, 168c become smaller towards the bottom of the piston 160. The piston 162 of FIG. 28 includes vertically arranged compartments 170a, 170b, 170c for holding dry powder medicament, and the compartments 170a, 170b, 170c become larger towards the bottom of the piston. The piston 164 of FIG. 29 includes vertically arranged shoulders 172 for holding dry powder medicament, and the shoulders are equally sized. The piston 166 of FIG. 30 includes vertically arranged compartments 174 for holding dry powder medicament, and the compartments are equally sized.

[0094] FIGS. 31 through 38 show further exemplary embodiments of medicament pistons 180, 182, 184, 186 constructed in accordance with the present invention. The piston 180 of FIGS. 31 and 32 has a circular cross-section and includes a single compartment 190 for holding dry powder medicament. The piston 182 of FIGS. 33 and 34 has a circular cross-section and includes vertically arranged shoulders 192 for holding dry powder medicament, and the shoulders 192 are equally sized. The piston 184 of FIGS. 35 and 36 has a rectangular cross-section and includes a single compartment

194 for holding dry powder medicament. The piston 186 of FIGS. 37 and 38 has a rectangular cross-section and includes vertically arranged compartments 196 for holding dry powder medicament, and the compartments 196 are equally sized.

[0095] FIG. 39 is a top perspective view of a further exemplary embodiment of a dose magazine 200 constructed in accordance with the present invention. The dose magazine 200 includes examples of variously shaped and arranged bores for receiving deployable medicament pistons, such as the medicament pistons of FIGS. 27 through 38, for example. The magazine 200 can include, for example, circular bores 202 that extend radially through the magazine or circular bores 204 that extend axially through the magazine. The magazine 200 can also include rectangular bores 206 that extend radially through the magazine or rectangular bores 208 that extend axially through the magazine. In addition, the magazine 200 can include a set 210 of radially arranged, rectangular bores or a set 212 of radially extending, rectangular bores.

[0096] FIG. 40 shows exemplary embodiments of a dose magazine 220, an actuator 222 for causing deployment of a medicament piston 224 from the magazine, and an adjustment mechanism 226 for adjusting the magnitude of deployment produced by the actuator, all constructed in accordance with the present invention. The adjustment mechanism 226 can be adjusted by a user to adjust the magnitude of deployment of the piston 224 produced by the actuator 222, so that the amount of dry powder medicament exposed for inhalation can be adjusted. The adjustment mechanism 226 include shims 228 which prevent full motion of actuator 222, and a user can dial in the number of shims 228 corresponding to a desired dose.

[0097] FIG. 41 is a top plan view of a further exemplary embodiment of a dose magazine 230 constructed in accordance with the present invention and including sets 232 of deployable medicament pistons, and FIG. 42 is a side perspective view of a portion of the dose magazine 230 of FIG. 41, wherein a set 232 of the medicament pistons 234a, 234b, 234c, 234d is shown deployed, or extended upwardly, from a top surface of the magazine. FIGS. 43 and 44 show a set 236 of actuators 238a, 238b, 238c, 238d for causing deployment of the set 232 of the medicament pistons 234a, 234b, 234c, 234d from the magazine. The actuators 238a, 238b, 238c, 238d can be manipulated as desired by a user to cause one or more of the pistons 234a, 234b, 234c, 234d to be deployed, so that the amount of dry powder medicament exposed for inhalation can be adjusted.

[0098] FIGS. 45 and 46 show a further exemplary embodiment of a dose magazine 240 constructed in accordance with the present invention and including bores 242 for receiving deployable medicament pistons. The bores 242 extend radially with respect to an axis A of the magazine 240.

[0099] FIGS. 47 and 48 show another exemplary embodiment of a dose magazine 250 constructed in accordance with the present invention and including bores 252 for receiving deployable medicament pistons. The bores 252 extend radially and at an angle with respect to an axis A of the magazine 250.

[00100] FIG. 49 show an additional exemplary embodiment of a dose magazine 260 constructed in accordance with the present invention and including bores 262 for receiving deployable medicament pistons. The bores 262 extend tangentially with respect to the magazine 260.

[00101] FIG. 50 show a further exemplary embodiment of a dose magazine 270 constructed in accordance with the present invention and including bores 272 for receiving deployable medicament pistons. The bores 272 are positioned at an outer circumference of the magazine 270 and extend axially with respect to an axis A of the magazine.

[00102] FIG. 51 shows a further exemplary embodiment of a rotatable dose magazine 280 constructed in accordance with the present invention and including radially extending teeth 282 for engaging a pawl 284, as shown, to prevent reverse rotation of the magazine 280 and to provide an indication of the advancement of a final medicament reservoir 286 of the magazine. This mechanism can be used to increase the force required to advance the magazine 280, increase noise or vibration, or provide other indication that the last medicament reservoir 286 is approaching and the inhaler should be refilled or replaced.

[00103] FIGS. 52 and 53 show an exemplary embodiment of a pawl 294 constructed in accordance with the present invention, for engaging a dose magazine 290. The pawl 294 can be adapted to provide a different sounding noise upon the advancement of a final medicament reservoir 296 and extending tooth 292 of the magazine 290.

[00104] FIG. 54 shows another exemplary embodiment of a rotatable dose magazine 300 constructed in accordance with the present invention and including radially extending medicament

dose containers 302 and a fixed blade 304 for successively opening the dose containers upon rotation of the magazine.

[00105] FIG. 55 shows an exemplary embodiment of a straw 310 constructed in accordance with the present invention and including medicament dose containers 312, and wherein an exemplary embodiment of a blade 314 constructed in accordance with the present invention for successively opening the dose containers 312 upon linear movement of the straw 310 is shown.

[00106] FIG. 56 shows another exemplary embodiment of a straw 320 constructed in accordance with the present invention and including medicament dose containers 322, and wherein parallel layers 324, 326 of the straw are peeled apart and wound to cause linear movement of the straw 320 and successive opening of the dose containers 322 contained between the layers 324, 326.

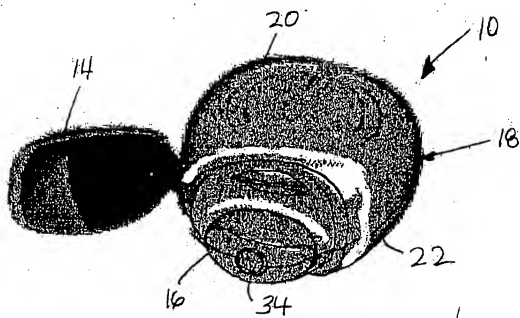
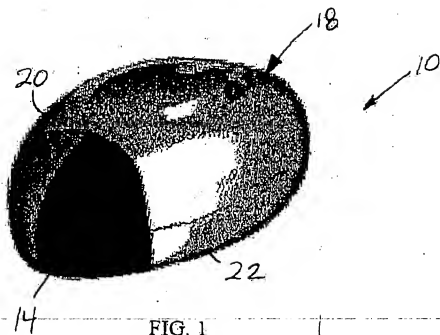
[00107] FIG. 57 shows an exemplary embodiment of a medicament dose carrier 330 constructed in accordance with the present invention and having doses 332 of medicament attached to a surface of the carrier 330. The carrier 330 is made of elastic material and is drawn around a sharp corner 334 to successively release the doses 332 of the medicament from the carrier 330 as the carrier is bent around the corner 334.

[00108] FIG. 58 shows a further exemplary embodiment of a straw 340 constructed in accordance with the present invention and including medicament dose containers 342. The straw 340 is drawn around a sharp corner 344 to successively open the dose containers 342 as the containers are bent around the corner.

[00109] FIGS. 59 and 60 are sectional views of portions of a filling nozzle 400 and a dry powder medicament dose magazine 410 illustrating exemplary embodiments of a method for filling reservoirs 412 of the magazine 410 with medicament carried out in accordance with the present invention. The method includes providing spacing members 420 between a surface 402 of the nozzle 400 and a surface 414 of the magazine 410, so that air flow is permitted between the nozzle 400 and the magazine 410 during filling of the reservoir 412. In the embodiment of FIG. 59, the spacing members 420 are provided as a unitary piece of the surface 402 of the nozzle 400. In the embodiment of FIG. 60, the spacing members 420 are provided as a unitary piece of the surface 414 of the magazine 410.

**[00110]** It should be understood that the foregoing detailed description and exemplary embodiments are only illustrative of a dry powder medicament inhaler and elements thereof according to the present invention. Various alternatives and modifications to the presently disclosed inhaler and inhaler elements can be devised by those skilled in the art without departing from the spirit and scope of the present invention. Accordingly, the present invention is intended to embrace all such alternatives and modifications that fall within the spirit and scope of the invention as disclosed herein.

1 of 16



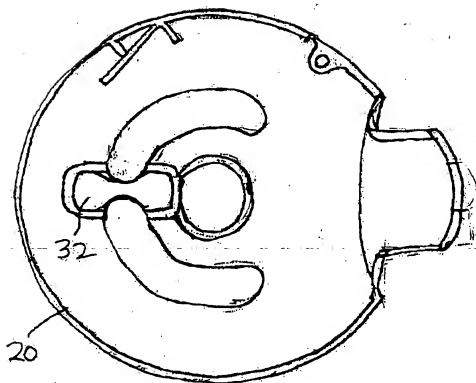


FIG. 3

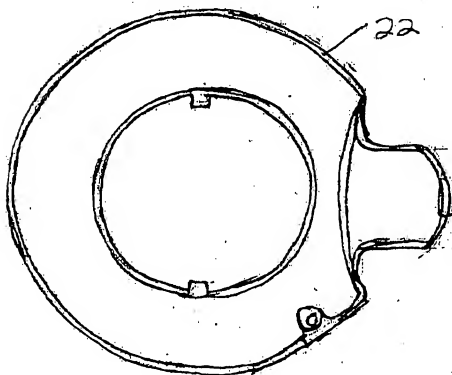


FIG. 4



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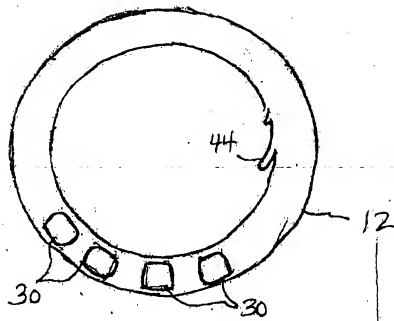


FIG. 5

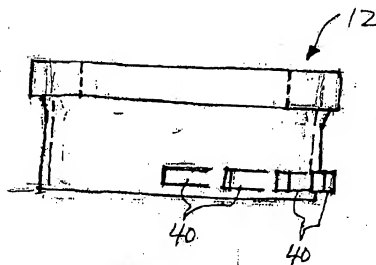


FIG. 6

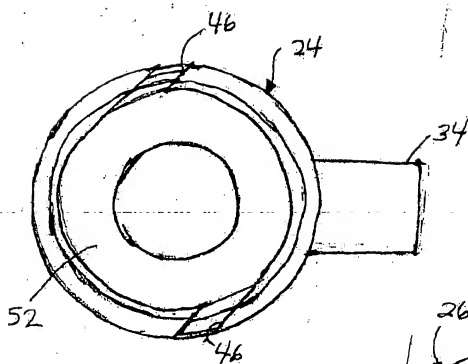


FIG. 7

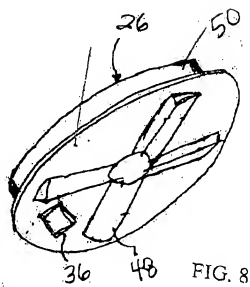


FIG. 8

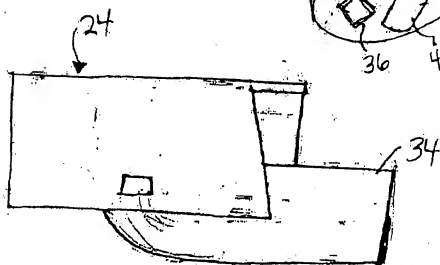


FIG. 9

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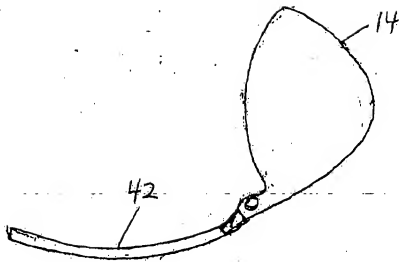


FIG. 10

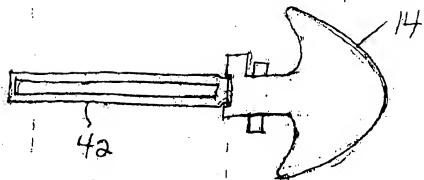


FIG. 11

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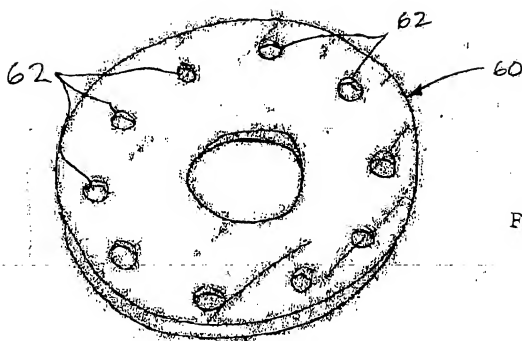


FIG. 14

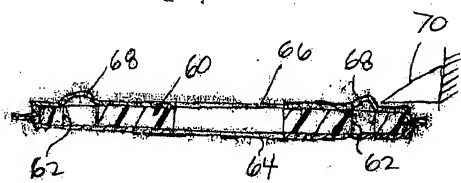


FIG. 13

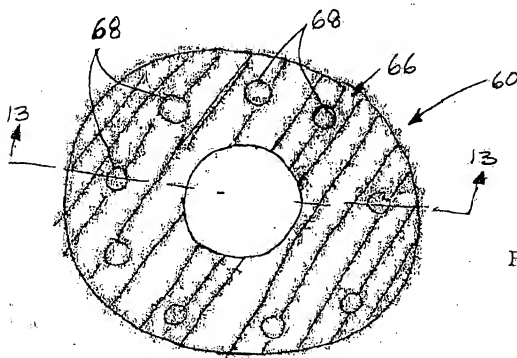


FIG. 12

FIG. 15

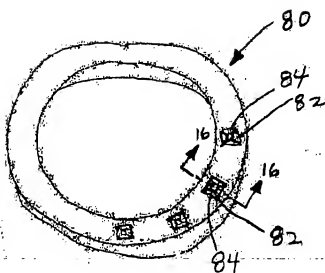


FIG. 16

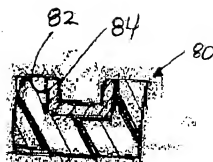


FIG. 17

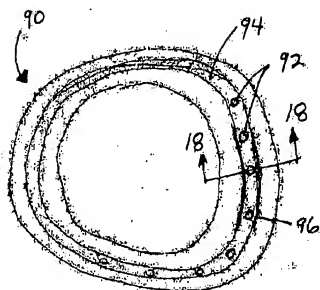


FIG. 18

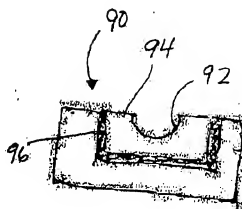
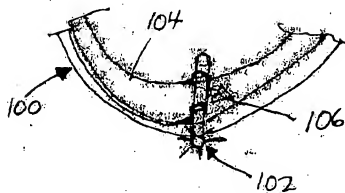


FIG. 19



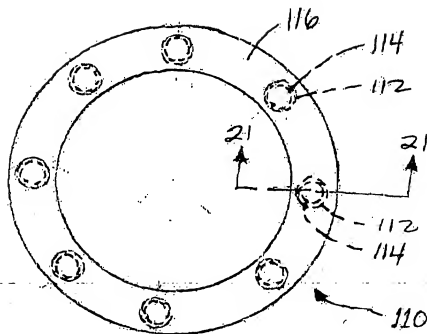


FIG. 20

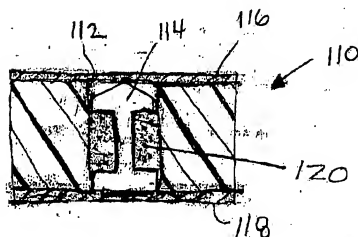


FIG. 21

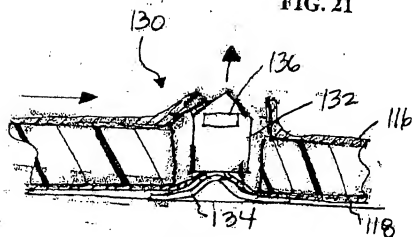


FIG. 22

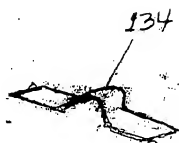


FIG. 23

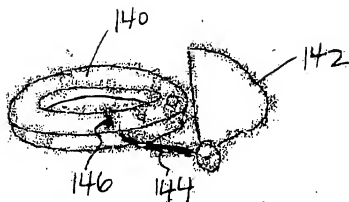


FIG. 24

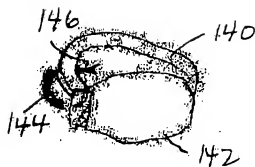


FIG. 25

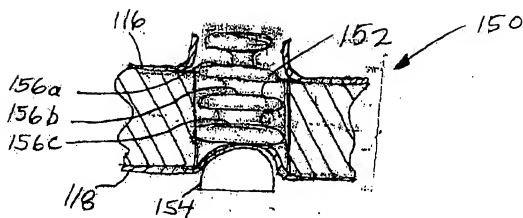


FIG. 26

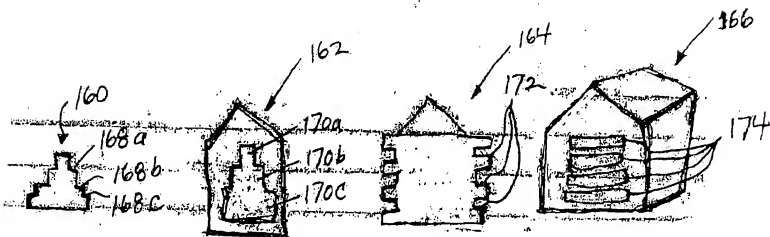


FIG. 27

FIG. 28

FIG. 29

FIG. 30

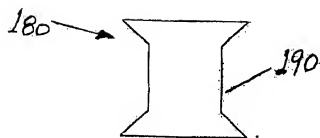


FIG. 31

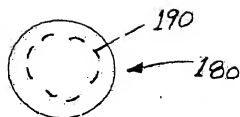


FIG. 32

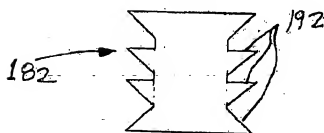


FIG. 33

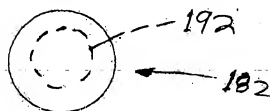


FIG. 34

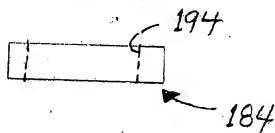
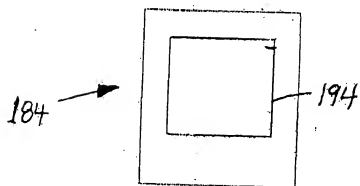


FIG. 36

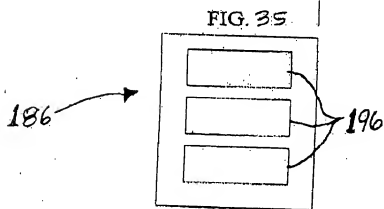


FIG. 37

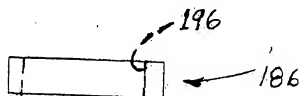


FIG. 38



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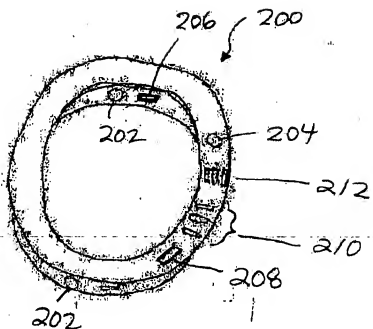


FIG. 39

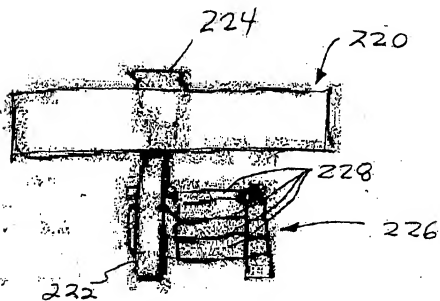


FIG. 40

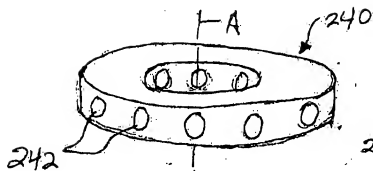


FIG. 45

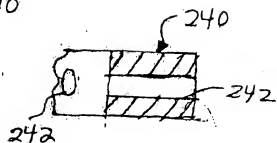


FIG. 46

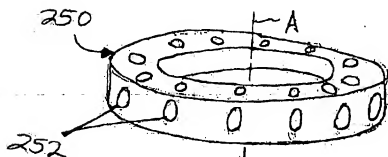


FIG. 47

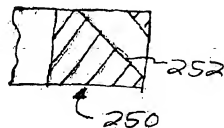


FIG. 48

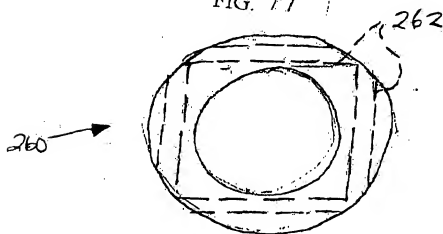


FIG. 49

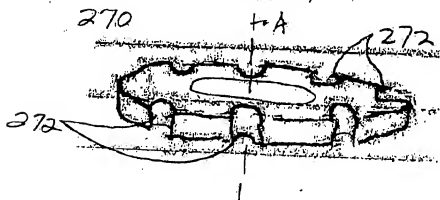


FIG. 50

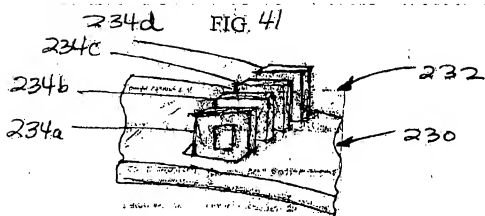
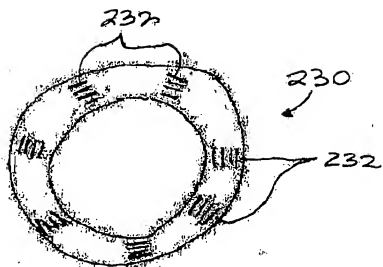


FIG. 42

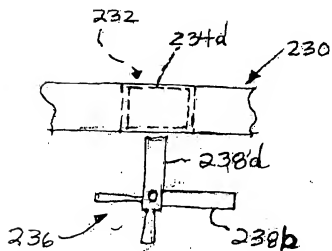


FIG. 43

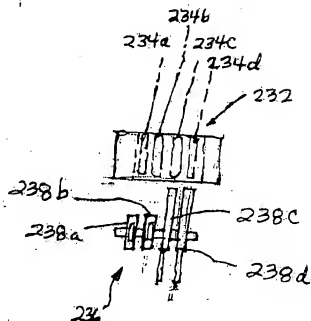


FIG. 44

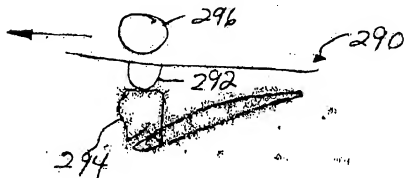
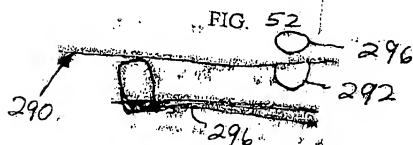
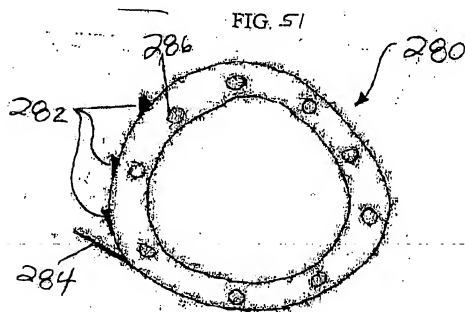


FIG. 53

FIG. 54

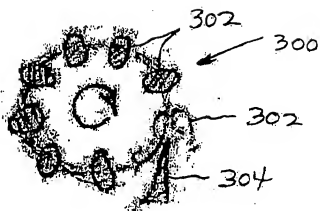


FIG. 55

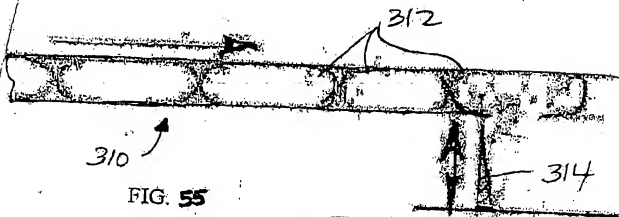


FIG. 56

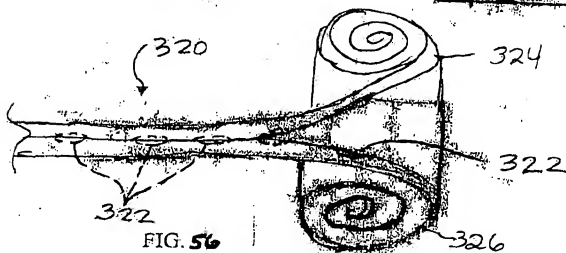


FIG. 57

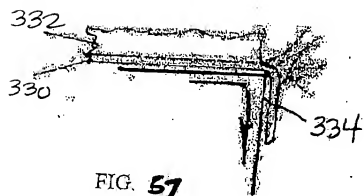
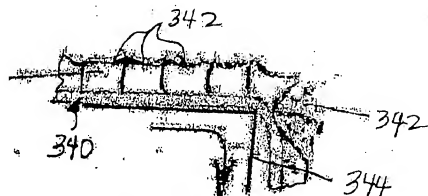


FIG. 58



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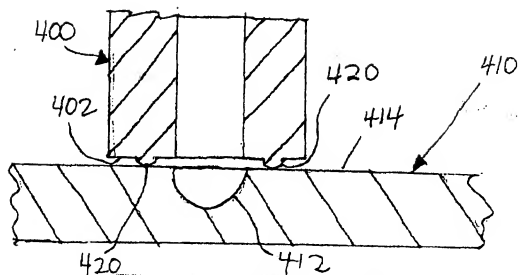


FIG. 59

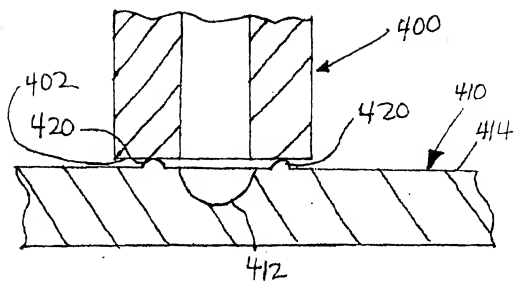


FIG. 60